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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,104	09/25/2006	Wouter De Graaff	2004.834US	7020

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EXAMINER	
DICKINSON, PAUL W	
ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
01/11/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@spcorp.com

Office Action Summary	Application No.	Applicant(s)	
	10/594,104	DE GRAAFF ET AL.	
	Examiner	Art Unit	
	PAUL DICKINSON	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13-16 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11, 13-16 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 11/9/2010, have been fully considered but they are not deemed to be fully persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to Arguments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 1-11, 13-16 and 21 under 35 U.S.C. 103(a) as being unpatentable over EP 0876815 (EP '815) is maintained.

Applicant argues the following points: The product Nuvaring® represents a commercially available embodiment of the EP '815 drug delivery system. The instant specification indicates that the progestogenic compound (i.e. etonogestrel) in Nuvaring® is present in 0.69 wt%, which is above the saturation level at 25 °C of 0.35 wt%. The package insert indicates that the product must be stored at 2-8 °C, and thus it is clear that Nuvaring® is distinct from the instant invention, which requires the drug delivery system be physically stale when stored at or above room temperature. The instant

invention requires the "progestogenic compound being dissolved in a core of a thermoplastic polyethylene vinylacetate copolymer at a concentration below the saturation level at 25 °C." This range is distinct from the range of EP '815, which teaches the thermoplastic polyethylene vinylacetate copolymer is at a relatively low degree of supersaturation, the concentration being above the saturation level at 25 °C.

Applicant's arguments have been fully considered but are not found persuasive. EP '815 strongly suggests concentration values at the saturation level at 25 °C. The instant claims are to concentrations just under the saturation level at 25 °C.

> "Similarly, a *prima facie* case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are lose enough that one skilled in the art would have expected them to have the same properties. Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ 73 (Fed. Cir. 1985)." MPEP § 2144.05, I.

In the instant case, the difference between the concentration values claimed by Applicant and those taught by EP '815 are different by a fraction of a wt%. For illustrative purposes only, in the case of etonogestrel, which has a saturation level at 25 °C of 0.35%, the teaching of EP '815 leads the skilled artisan to 0.35 wt% (to the saturation level at 25 °C). Applicant's claims require the concentration to be any possible value under the saturation level at 25 °C, for etonogestrel, under 0.35 wt%. Such a range includes 0.34 wt%. In this illustration, the difference between 0.34 wt% (encompassed by Applicant's claimed range) and 0.35 wt% (encompassed by the range taught by EP '815) differs by 0.01 wt%. The ordinary artisan would not expect such a small change in concentration would result in different physical characteristics of the drug delivery system.

EP ‘815 strongly suggests concentration values at the saturation level at 25 °C for the following reasons: The progestogenic compound is dissolved in the core polymer in a relatively low degree of supersaturation, preferably being about 1 to about 6 times of the amount of weight necessary for obtaining the saturation concentration of said progestogenic steroid in said core polymer at 25 °C (page 2, line 54 to page 3, line 4; claim 4). “About 1 times the amount of weight necessary for obtaining the saturation concentration of said progestogenic steroid in said core polymer at 25 °C" not only strongly suggests concentration values at the saturation level at 25 °C, but the breath of "about" suggests the values could even be less than the saturation level at 25 °C. In other words “about 1 times” encompasses values under 1 times. Furthermore, EP ‘815 discloses that an essential element of the invention is for the progestogenic steroid dissolved in the core material to be present in a relatively low degree of supersaturation and EP ‘815 further discloses the importance of keeping the steroid dissolved in a low concentration to improve the shelf life of the product (page 4, lines 6-24; Reference Example). Accordingly, as values are taught around the saturation level at 25 °C, and as EP ‘815 teaches the importance of keeping the progestogenic steroid dissolved in a low concentration to improve the shelf life, the reference provides sufficient guidance to the ordinary artisan to optimize the progestogenic steroid concentration range to find values just below the saturation level at 25 °C, i.e. values “at a concentration below the saturation level at 25 °C”.

Regarding the product Nuvaring®, a reference may be relied on for all it teaches and is not limited to preferred embodiments and examples. EP '815 strongly suggests concentration values at and just below the saturation level at 25 °C.

Regarding the limitation "wherein the drug delivery system is physically stable when stored at or above room temperature", while EP '815 does not disclose this properties, the drug delivery system rendered obvious by EP '815 (i.e. the drug delivery system having progestogenic compound concentrations just below the saturation level at 25 °C), is structurally identical to the instant drug delivery system. As a composition cannot be separated from its properties, and the drug delivery system rendered obvious by EP '815 is identical to the instant drug delivery system, the instant shelf life properties must be inherent in the drug delivery system rendered obvious by EP '815. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). MPEP § 2112.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

January 4, 2011